

Appl. No. 10/662,923  
Amdt. dated November 30, 2004  
Reply to Office Action Mailed October 25, 2004

**REMARKS**

The above-referenced application has been reviewed in light of the Office Action mailed October 25, 2004. By the present amendment, the Applicant has amended claim 2, has canceled claim 10, and added new claim 13. Claims 1 and 6 were canceled by previous amendments. It is respectfully submitted that the claims pending in the application do not introduce new subject matter, are fully supported by the specification, and are patentable over the prior art. Prompt and favorable consideration of these claims is earnestly sought.

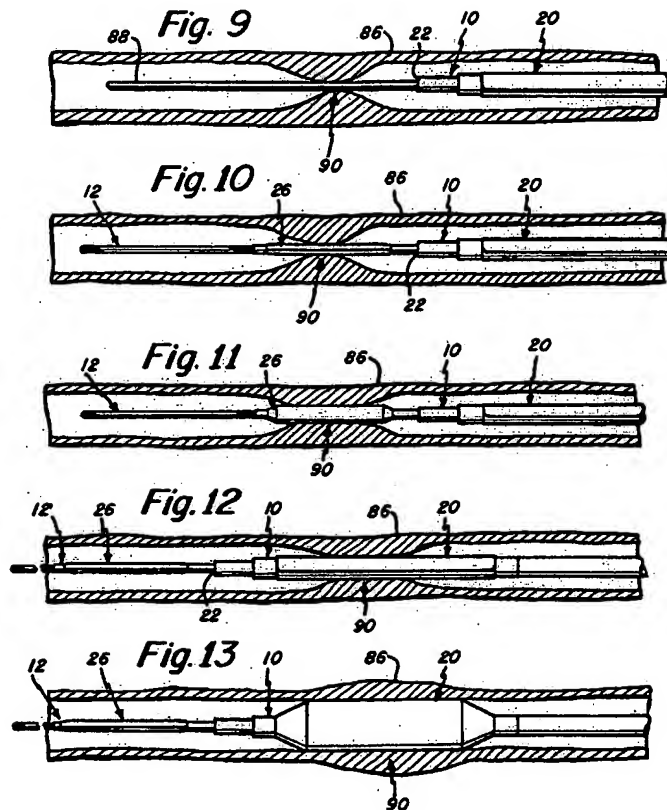
The Office Action rejected claims 2, 5, and 7-10 under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 5, 102,390 to Crittenden et al. (the '390 patent) in view of U.S. Patent No. 5,180,367 to Kontos et al. (the '367 patent). In the Office Action, it was stated that the '390 patent discloses a device having a first tubular member having an open proximal end, a first inflatable member, a second tubular member having open proximal and distal ends defining a bore therethrough, and a second inflatable member. In addition, the Office Action stated that the '390 patent does not disclose the first tubular member having an open distal end, but stated that the '367 patent discloses a device having an inner tubular member with an open distal end and it would have been obvious to make the device of the '390 patent with the open distal end of the '367 patent. In addition, it was stated that the slidable guide wire of the '390 patent is considered to be a surgical instrument.

As noted by the Office Action, the '390 patent is deficient in that it does not disclose the first tubular member having an open distal end, as required by amended claim 2. To overcome this deficiency, the disclosure of the '367 patent was combined with the disclosure of the '390 patent.

The disclosure of the '390 patent combined with the disclosure of the '367 patent, as suggested by the Office Action, does not suggest an apparatus for separating layers of tissue including, *inter alia*, first and second tubular members having open proximal and distal ends, "a first inflatable member disposed on the distal end of the first tubular member," "a second inflatable member disposed on the distal end of the second tubular member," and "wherein the first and second inflatable members are longitudinally spaced apart to define a working space therebetween, and when the first and second members are in the inflated state, movement of the first inflatable member towards the second inflatable member is capable of capturing body tissue therebetween" as now recited in amended claim 2.

The '390 patent relates to an angioplasty device having first and second inflatable members, a tubular member, and a guide wire extending therethrough. The distal end of the tubular member is a closed distal end, resulting from the guide wire being brazed or soldered in position (see Column 7, lines 22-23). In addition, the '390 patent discloses that the "diameter of the probe balloon 26, when fully inflated is just slightly greater than the outer diameter of the dilatation catheter 10 when the catheter balloon 20 is deflated" (see Column 6, lines 15-18). The structural relationship of the probe balloon with respect to the catheter balloon is illustrated in FIGS. 9-13 reproduced below. The '367 patent discloses a tubular member having an open distal

end so that it can slidably receive a guide wire.



As discussed hereinabove, the '390 patent discloses that the inflated probe balloon 26 has an outer diameter "just slightly greater" than the diameter of the catheter 10 when the catheter balloon 20 is in the uninflated state as shown in FIG. 11. Even if the probe balloon 26 and the catheter balloon 20 were both in the inflated state, the difference in their outer diameters is such that proximal movement of the probe balloon 26 is not capable of capturing tissue between the balloons. Specifically, since the diameter of the inflated probe balloon 26 is "just slightly greater" than the diameter of the catheter, the inflated probe balloon 26 would come into contact

with the distal end of the catheter 10 without capturing body tissue between the balloons as does an apparatus according to amended claim 2. Combining the disclosure of the '367 patent with the '390 patent does not overcome this deficiency. In particular, there is no suggestion in the combination of the '390 patent and the '367 patent for an apparatus including, *inter alia*, first and second tubular members having open proximal and distal ends, "a first inflatable member disposed on the distal end of the first tubular member," "a second inflatable member disposed on the distal end of the second tubular member," and "wherein the first and second inflatable members are longitudinally spaced apart to define a working space therebetween, and when the first and second members are in the inflated state, movement of the first inflatable member towards the second inflatable member is capable of capturing body tissue therebetween" as recited in amended claim 2.

Therefore, it is respectfully submitted amended claim 2 is not suggested by combination of the '390 patent and the '367 patent, and the rejection of the Office Action has been overcome. Since claims 5 and 7-10 depend from amended claim 2, it is respectfully submitted that the rejection of these claims has been overcome as well.

Claims 3 and 4 were rejected in the Office Action under 35 U.S.C. § 103 (a) as being unpatentable over the '390 patent in view of the '367 patent and further in view of U.S. Patent No. 4,981,478 to Evard et al (the '478 patent). The Office Action stated that the '390 patent does not disclose an inner member defining an annular space with the first tubular member. According to the Office Action, the '478 patent discloses a balloon with an inner tubular member and an outer tubular member having an annular space therebetween.

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However, as discussed above, the '390 patent in combination with the '367 patent does not suggest the apparatus for separating layers of tissue that is recited in amended claim 2. The addition of the '478 patent does not overcome this deficiency. Since claims 3 and 4 depend from amended claim 2, it is respectfully submitted that these claims are not suggested by the '390 patent in view of the '367 patent and further in view of the '478 patent and the rejection of the Office Action has been overcome.

Claims 10 and 11 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over the '390 patent in view of the '367 patent and further in view of U.S. Patent No. 4,690,140 to Mecca (the '140 patent). Although the Office Action applied this combination of references to claims 10 and 11, it is believed that this combination of references should have been applied to claims 11 and 12. As discussed above, the '390 patent in combination with the '367 patent does not suggest the apparatus for separating layers of tissue that is recited in amended claim 2. The addition of the '140 patent does not overcome this deficiency. Claims 10-12 depend from amended claim 2. It is respectfully submitted that these claims are not suggested by the '390 patent in view of the '367 patent and further in view of the '140 patent for the reasons discussed above, and that the rejection of the Office Action has been overcome.

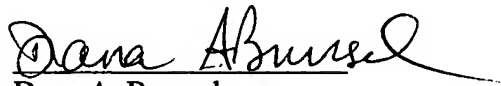
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New claim 13 depends directly from amended claim 2. As discussed hereinabove, the '390 patent, taken alone or in combination with the '367 patent and the '478 patent, does not suggest the apparatus for separating layers of tissue that is recited in amended claim 2.

Therefore, it is respectfully submitted that new claim 13 is patentable over the art of record.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application, namely claims 2-5, 7-9, and 11-13, are in condition for allowance. Should the Examiner desire a telephonic interview to resolve any outstanding matters, he is sincerely invited to contact the undersigned at (631) 501-5713.

Respectfully submitted,

  
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